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EXAMINER
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ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,035	SKANSEN ET AL.	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22,24-29,31,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22,24-29,31,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on November 25, 2008, Applicant amended claims 19-22, 24-29, 31, 33, and 34.

2. Applicant cancelled claims 23, 30, 32, and 35-37.

3. In the non-final rejection of August 27, 2008, Examiner rejected claim 37 under 35 USC 112, 2nd paragraph, for insufficient antecedent basis for claim terms. Applicant cancelled claim 37. Rejection is withdrawn.

4. Currently, claims 19-22, 24-29, 31, 33, and 34 are under examination.

Response to Arguments

5. Applicant's arguments, see pages 9-14, filed on November 25, 2008, with respect to the rejection(s) of claim(s) 19-37 under Uldall, Griego et al, Balbierz et al, and/or Porter have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Porter (US 2003/0216685), and further in view of Griego et al (US 6,663,596) and Kolln (US 4,722,734).

Claim Objections

6. Claim 24 is objected to because of the following informalities:

In regards to claim 24, "**an** external pump device" should be corrected as "**the** external pump device", since said component has previously been introduced as "an external pump device" in prior claim 19.

In regards to claim 25, "said device" should be corrected as "said **catheter** device" since there are two devices in claim 19: a catheter device and an external pump device.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 19, the claim element "control means" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. It is only recited in the specification that the control means is adapted to control the pumping means. Hence, the specification does not contain a recitation of the structure associated with the control means (page 6, lines 6-25).

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 19-22, 24, 25, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 2003/0216685), and further in view of Griego et al (US 6,663,596) and Kolln (US 4,722,734).

In regards to claim 19, Porter teaches an infusion system comprising a catheter device (Figures 1 and 1A-1D, catheter device [10]) comprising:

a. an outer catheter (outer tubular element [20]) provided with one outer catheter lumen (lumen [28]) with a distal outer catheter outflow opening (opening at distal tip [25]), and an inner catheter (inner tubular element [22]) provided with at least one inner catheter lumen (lumen [34]) with at least one distal inner catheter outflow opening (opening at distal tip [31]), said inner catheter is adapted to be detachably arranged in said outer catheter lumen (Figure 1B), said inner catheter outflow opening is located proximally said outer catheter outflow opening when the catheter device is adapted to be used for administration of liquid substances to a patient (Figure 1)

b. wherein the infusion system further comprises an external pump device including a pumping means and a reservoir means (first supply [34] and second supply [36] which contain first fluid component [12] and second fluid component [14], respectively; either of supplies [34][36] may be a pump) (paragraph [0038])

c. wherein a liquid pulse of a liquid substance (second fluid component [14]) through the inner catheter lumen [34] is followed in time sequence by a liquid pulse of a flushing liquid (first fluid component [12]) applied through the outer catheter lumen [28], in order to make the liquid substance reach a target area of administration (paragraph [0061])

Porter is silent about whether the external pump device [34][36] comprises a control means, wherein said control means controls the pumping means such that said substance is administered as a pulsed flow sequence of liquid substance comprising a predetermined number of liquid pulses. Griego et al teaches an infusion system (Figures 10A-10B, delivery system [16]) wherein an external pump device comprises a pumping means (first pump [183] and second pump [283]), a reservoir means (reservoirs [196][296]), and a control means (control system [298]) (column 8, lines 19-43). However, Griego et al does not teach that said control means [298] controls the pumping means [183][283] such that a substance (second material, not referenced) is administered as a pulsed flow sequence of liquid substance comprising a predetermined number of liquid pulses, since Griego et al teaches a continuous flow sequence, not a pulsed flow sequence (column 8, lines 19-43). However, as shown by Kolln, it was common knowledge in the art at the time the invention was made to program the pumping means of an external pump device, via control means, to perform pulsatile flow of a liquid substance: Kolln teaches an external pump device (Figures 1-4), wherein control means (electronic control [6] with microcomputer [28]) control one pump [4] such that a substance is administered as a pulsed flow sequence of liquid substance comprising a predetermined number of liquid pulses (Abstract). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the external pump device, of the infusion system of Porter, with a control means for two pumps of a pumping means, as taught by Griego et al, and a control means that directs a substance to pulsatile flow, as taught by Kolln, as such will enable the user to control and monitor the amount of substances infused into the patient based on computerized control of the pressure and material flow by a control means (Griego et al, column 8, lines 19-

43), and the control means can easily program the pump means to administer intermittent pulsatory flow of substances as common practice in the art (Kolln, Abstract). *In Applicant's specification, the pumping means is at least two pumps, and the reservoir means is one or more reservoirs. The specification states that the control means is adapted to control the pumping means; however, the specification does not contain a recitation of the structure associated with the control means (page 6, lines 6-25).*

In regards to claim 20, in a modified system of Porter, Griego et al, and Kolln, Porter teaches that said inner catheter [22] is coaxially arranged with regard to said outer catheter [20] (Figure 1).

In regards to claim 21, in a modified system of Porter, Griego et al, and Kolln, Porter teaches that at least one substance [14], adapted to be administered, is active, and is a pharmaceutical preparation for therapeutic or diagnostic use (Abstract)(paragraphs [0012][0061]).

In regards to claim 22, in a modified system of Porter, Griego et al, and Kolln, Porter teaches that said substance [14] is administered by said inner catheter [22] (paragraph [0039]).

In regards to claim 24, in a modified system of Porter, Griego et al, and Kolln, Porter teaches that the outer and inner catheters [20][22] comprises at their respective proximal ends [26][32] first connector means (connector [23]) for connection to an external pump device having one or more reservoirs [34][36] for substances and flushing liquids (paragraph [0038]). However, in Applicant's specification, the first connector means is a pair of connector parts (page 10, lines 6-9). Porter only teaches that the first connector means is one connector [23]. Griego et al teaches a catheter device (Figure 10a-10b, delivery system [16]) with outer and inner

catheters (first elongated member [100] and second elongated member [200]) having first connection means (connection ports or seals [170][270]) at their respective proximal ends for connection to an external pump device (first pump [183] and second pump [283]) having reservoirs (reservoirs [196][296]) for substances and flushing liquids (first and second materials, *not referenced*). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute the one connector, of the catheter device of the modified infusion system of Porter, Griego et al, and Kolln, with two connectors of a first connection means, as taught by Griego et al, as providing each one of the inner and outer catheters with their own separate connector to a respective reservoir of the external pump device will allow each one of the catheters to be connected and disconnected from the external pump device without connecting or disconnecting the other one of the catheters from the external pump device (i.e. with respect to the one connector of Porter, both catheters must be connected or disconnected from the external pump device at the same time since there is only one connector) (Griego et al, column 8, lines 21-27). *In Applicant's specification, the first connector means is a pair of connector parts (page 10, lines 6-9).*

In regards to claim 25, in a modified system of Porter, Griego et al, and Kolln, Porter teaches that said device [10] is provided with a second connector means (connector [23]) making it possible to detach said inner catheter [22] and replace it (Figure 1B).

In regards to claim 34, in a modified system of Porter, Griego et al, and Kolln, Porter teaches that the volume of a liquid pulse of the substance [14] is approximately the same as the volume (mixing zone [38]) defined in said outer catheter lumen [28] between the inner catheter outflow opening and the outer catheter outflow opening (paragraph [0061]).

11. Claims 26-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter, Griego et al, and Kolln, as applied to claims 19 and 25 above, and further in view of Balbierz et al (US 5,156,596).

In regards to claim 26, in a modified system of Porter, Griego et al, and Kolln, Porter does not teach that said second connector means [23] is partly integrated in a Y-connection. Balbierz et al teaches a catheter device (Figures 3-5, catheter assembly [10]) with a second connector means (inner lumen positioning assembly [38] with Luer locking mechanism [66]) for detachably arranging an inner catheter [52] within an outer catheter [28], wherein the second means [38] comprises a Y-connection ("Y-shape") (column 7, lines 22-53). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the second connector means, of the modified system of Porter, Griego et al, and Kolln, with a second connector means having a Y-connection, as taught by Balbierz et al, as the second connector means having a Y-connection as the two proximal access regions of the Y-connection will allow non-compatible medicaments to be introduced into the body at a spaced distance apart from one another (column 7, lines 22-53).

In regards to claims 27-29, in a modified system of Porter, Griego et al, Kolln, and Balbierz et al, Porter teaches that the second connector means [23] includes a first fastening means (indentation [60]) at the proximal end of said inner catheter [22] adapted to co-operate with a second fastening means (ridge [62]) integrated with an opening in the outer catheter wall [20] such that when said first and second fastening means are attached to each other the catheter is in a substance administration state (Figure 1).

In regards to claim 31, in a modified system of Porter, Griego et al, and Kolln, Porter does not teach that the inner catheter [22] comprises two lumen, as Porter only teaches one inner catheter lumen [34]. Balbierz et al teaches a catheter device (Figure 11) comprising an inner catheter (inner cannula [52]) with two lumen (passages [90][92]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the inner catheter, of the modified system of Porter, Griego et al, and Kolln, with two lumen, as taught by Balbierz et al, as two lumen will allow the inner catheter to deliver two different substances to the patient, for example, if so desired by the user.

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Porter, Griego et al, and Kolln, as applied to claim 19 above, and further in view of Uldall (US 4,493,696).

In regards to claim 33, in a modified system of Porter, Griego et al, and Kolln, Porter does not teach that all surfaces in contact with the active substance [14] in the catheter device [10] are made of or covered by tetrafluoro polyethylene. Uldall teaches a catheter device (Figures 1-5, cannula [10]), wherein all surfaces in contact with an active substance in the catheter device [10] are made of tetrafluoro polyethylene (column 3, lines 16-24). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter device, of the modified system of Porter, Griego et al, and Kolln, to be made of tetrafluoro polyethylene, as tetrafluoro polyethylene has known biocompatibility for residence in a patient's body over extended periods of time (column 3, lines 16-24).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Cragg et al (US 6,146,373) and Roche (US 5,558,646).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
02/20/2009

/Kevin C. Sirmons/
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